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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/520,856	03/07/2000	Olexander Hnojewyj	1849.16102-A CIP 2	8986

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/520,856	HNOJEWYJ ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,12,13,15,31,32,44,81-86 and 109-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31,32 and 109-121* is/are allowed.

6)☒ Claim(s) *6,7,12,13,15,44 and 81-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 March 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The terminal disclaimer filed September 22, 2003 is approved.

2. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 15, line 7, the language "group consisting essentially of" is unclear because it is not standard Markush language, and it is not clear whether the cross-linking group must be selected from the listed groups or not. It is suggested that "essentially" be deleted from the claim.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44 and 81-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the new claim limitations in claim 44 directed to sealing gas leaks, sealing liquid leaks, or sealing solid leaks in general. Note that the original disclosure is limited to sealing tissue from gas leaks, sealing tissue from liquid leaks, and sealing tissue from solid leaks (compare originally filed claims 50, 53, and 56).

4. Claims 7 and 82 are objected to because of the following informalities: At claim 7, line 2, the SEQ ID NO which was inserted into the claim by the preliminary amendment filed May 30, 2002 needs to be re-inserted back into the claim. See 37 CFR 1.821(d). At claim 82, line 3,

"collagenase" is misspelled. A SEQ ID NO needs to be inserted after the tetrapeptide amino acid sequence recited in the claim. See 37 CFR 1.821(d). Appropriate correction is required.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 44 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,371,975. Although the conflicting claims are not identical, they are not patentably distinct from each other. Because the protein solutions, polymer solutions, degradation control regions, and cross-linking groups are the same in the claimed invention of the '975 patent as in the instant claimed invention, inherently the claimed invention of the '975 patent will have the same degradation periods and cross-linking periods as are claimed in the instant claims. While the '975 patent does not claim its individual components in the form of a system including instructions for use, it would have been obvious to one of ordinary skill in the art to package the components of the materials claimed in the '975 patent in the form of a system including instructions for use, because it is known and routine in the chemical and pharmaceutical arts to package reagents in the form of a system including instructions for use because this packaging form makes the storage, transportation, preparation, and use of the components easier for the artisan. With respect to the

text per se of the instructions, this does not impart patentability to compositions or articles of manufacture where the compositions or article of manufacture are otherwise anticipated by or obvious over the art.

7. Claims 12, 13, 15, 44, and 83-86 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 09/780,014. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '014 application anticipate instant claims 12, 13, and 15. Because the protein solutions, polymer solutions, degradation control regions, and cross-linking groups are the same in the claimed invention of the '014 application as in the instant claimed invention, inherently the claimed invention of the '014 application will have the same degradation periods and cross-linking periods as are claimed in the instant claims. With respect to instant claims 44 and 83-86, while the '014 application does not claim the text of the instructions recited in each of these claims, this does not impart patentability to compositions or articles of manufacture where the compositions or article of manufacture are otherwise anticipated by or obvious over the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. The effective filing date of instant claims 31, 32, 44, 81-86, 120, and 121 is deemed to be March 7, 2000, the filing date of the instant application. Instant claims 31, 32, 120, and 121 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/283,535 because the parent application '535, under the test of 35 U.S.C. 112, first paragraph, does not disclose a hydrophilic polymer with a functionality of at least three wherein

the hydrophilic polymer comprises at least one hybrid protein or at least one synthetic amino acid sequence. Instant claims 44 and 81-86 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/283,535 because the parent application '535, under the test of 35 U.S.C. 112, first paragraph, does not disclose all of the uses recited in instant claim 44, i.e. does not disclose instructions for applying the mixture to seal tissue from gas leaks, to seal tissue from solid leaks, to prevent post-operative adhesions, to repair a tissue void, to augment tissue, to embolize an arterio-venous malformation, to fill an aneurysm, to deliver a pharmaceutical, and to deliver cells.

The effective filing date of instant claims 6, 7, 12, 13, and 15 is deemed to be November 6, 1998, the filing date of grandparent application 09/188,083. Instant claims 6, 7, 12, 13, and 15 is deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the grandparent application '083 because the grandparent application '083, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 44 and 85 are rejected under 35 U.S.C. 103(a) as being obvious over Doi et al (U.S. Patent No. 4,839,345). Doi et al teach protein solutions crosslinked with polymer solutions wherein the crosslinking polymer can have a functionality of three or more, wherein from 1 to

3000 ethylene glycol units can be present in the polymer, and wherein a diacid links the crosslinking group to the ethylene glycol groups, and wherein the cross-linking group can be an ester of an N-hydroxysuccinimide. The protein can be, e.g., gelatin or albumin. The cross-linking groups react with amino groups contained in the protein to form a biocompatible adhesive gel. See, e.g., column 2, lines 36-43; Preparation Example 3; Example 3; and the claims. Gelatin is a water-soluble derivative of collagen. In view of the similarity in reactants, preparation method, and structure between the gel of Doi et al and Applicants' claimed biocompatible material, the gel of Doi et al is deemed inherently to have the same degradation periods and cross-linking periods as are claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the gels of Doi et al and Applicants' claimed biocompatible materials to shift the burden to Applicants to provide evidence that the claimed biocompatible materials are unobviously different than those of Doi et al. Doi et al do not teach the reactants in kit form with instruction for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the reactants required by Doi et al in the form of a kit including instructions for use, because it is known and routine in the chemical and pharmaceutical arts to package reagents in the form of a kit including instructions for use because this packaging form makes the storage, transportation, preparation, and use of the components easier for the artisan. With respect to the text per se of the instructions, this does not impart patentability to compositions or articles of manufacture where the compositions or article of manufacture are otherwise anticipated by or obvious over the art.

11. Claims 6 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by the WO Patent Application 98/12274. The WO Patent Application '274 teaches forming a gel

comprising crosslinked proteins. In particular, the protein source can be an albumin solution, and the crosslinking agent can be a hydrophilic polymer such as polyethylene glycol with a functionality of three or more and comprising a biodegradable extension component and a reactive moiety such as carbodiimidazole (which reacts with amines), sulfonyl chloride (which reacts with amines), chlorocarbonates (which react with amines), n-hydroxysuccinimidyl ester (which reactants with amines), and maleimides (which react with thiols). The biodegradable moiety can be peptidic such that it is enzymatically hydrolyzable, e.g., by metalloproteinases and collagenases. See, e.g., page 17, line 3 - page 20, line 11; page 32, line 1 - page 33, line 28; claims 40-43; and Figure 5.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/12274 as applied against claims 6 and 12 above, and further in view of Kennedy et al (U.S. Patent No. 5,618,790). The WO Patent Application '274 teaches a biodegradable extension moiety which is enzymatically hydrolyzable by metalloproteinases and collagenases, but does not teach Leu-Gly-Pro-Ala or Gly-Pro-Lys as particular biodegradable extension moieties. Kennedy et al teach peptides comprising Leu-Gly-Pro-Ala and Gly-Pro-Lys as biodegradable linking agents which are cleaved in vivo by proteases such as collagenase and plasmin. See, e.g., column 5, line 60 - column 6, line 57. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the peptides taught by Kennedy et al as the biodegradable extension moiety of the WO Patent Application '274 because the peptides taught by Kennedy et al exhibit the same function and are used for the same in vivo biodegradation purpose required for the biodegradable extension moiety of the WO Patent

Application '274, and because substitution of a known species for a genus is prima facie obvious.

13. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/12274 as applied against claims 6 and 12 above, and further in view of Rhee et al (U.S. Patent No. 5,874,500). The WO Patent Application '274 teaches a reactive moiety to establish crosslinking, but does not teach the particular reactive moieties specified in instant claims 13 and 15. Rhee et al teach forming crosslinked polymer compositions between a polymer comprising nucleophilic groups, which can be a synthetic polypeptide, and a polymer comprising electrophilic groups, which can be polyethylene glycol. Rhee et al teach that the electrophilic groups can be vinyl sulfone, orthopyridyl disulfide, and aldehyde. See, e.g., the Abstract; column 4, lines 26-55; and column 7, line 52 - column 8, line 67. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the electrophilic groups of Rhee et al, including vinyl sulfone, orthopyridyl disulfide, and aldehyde, as the reactive moiety of the WO Patent Application '274 because the electrophilic groups of Rhee et al exhibit the same function and are used for the same polymer crosslinking purpose required for the reactive moiety of the WO Patent Application '274, and because the substitution of a known species for a genus is prima facie obvious.

14. Claims 44, 81, 83, and 85 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/12274. Application of the WO Patent Application '274 is the same as in the above rejection of claims 6 and 12. The WO Patent Application '274 does not teach the reactants in kit form with instruction for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the reactants required by the

WO Patent Application '274 in the form of a kit including instructions for use, because it is known and routine in the chemical and pharmaceutical arts to package reagents in the form of a kit including instructions for use because this packaging form makes the storage, transportation, preparation, and use of the components easier for the artisan. With respect to the text per se of the instructions, this does not impart patentability to compositions or articles of manufacture where the compositions or article of manufacture are otherwise anticipated by or obvious over the art.

15. Claim 82 is rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/12274 as applied against claims 44, 81, 83, and 85 above, and further in view of Kennedy et al (U.S. Patent No. 5,618,790). The WO Patent Application '274 teaches a biodegradable extension moiety which is enzymatically hydrolyzable by metalloproteinases and collagenases, but does not teach Leu-Gly-Pro-Ala or Gly-Pro-Lys as particular biodegradable extension moieties. Kennedy et al teach peptides comprising Leu-Gly-Pro-Ala and Gly-Pro-Lys as biodegradable linking agents which are cleaved in vivo by proteases such as collagenase and plasmin. See, e.g., column 5, line 60 - column 6, line 57. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the peptides taught by Kennedy et al as the biodegradable extension moiety of the WO Patent Application '274 because the peptides taught by Kennedy et al exhibit the same function required for the biodegradable extension moiety of the WO Patent Application '274, and because substitution of a known species for a genus is prima facie obvious.

16. Claims 84 and 86 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/12274 as applied against claims 44, 81, 83, and 85 above, and further in

view of Rhee et al (U.S. Patent No. 5,874,500). The WO Patent Application '274 teaches a reactive moiety to establish crosslinking, but does not teach the particular reactive moieties specified in instant claims 84 and 86. Rhee et al teach forming crosslinked polymer compositions between a polymer comprising nucleophilic groups, which can be a synthetic polypeptide, and a polymer comprising electrophilic groups, which can be polyethylene glycol. Rhee et al teach that the electrophilic groups can be vinyl sulfone, orthopyridyl disulfide, and aldehyde. See, e.g., the Abstract; column 4, lines 26-55; and column 7, line 52 - column 8, line 67. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the electrophilic groups of Rhee et al, including vinyl sulfone, orthopyridyl disulfide, and aldehyde, as the reactive moiety of the WO Patent Application '274 because the electrophilic groups of Rhee et al exhibit the same function and are used for the same polymer crosslinking purpose required for the reactive moiety of the WO Patent Application '274, and because the substitution of a known species for a genus is prima facie obvious.

17. Applicant's arguments filed September 22, 2003 have been fully considered but they are not persuasive.

With respect to the rejection of claim 44 on the basis of obviousness-type double patenting over U.S. Patent No. 6,371,975 (see section 6 above), Applicants have neither provided a terminal disclaimer over the '975 patent nor explained how the broadened claim avoids the conclusion of obviousness set forth in the rejection.

With respect to the rejection of claims 44 and 85 over Doi et al (U.S. Patent No. 4,839,345), Applicants do not appear to have provided any argument or amendment which would overcome or avoid this rejection.

18. Claims 31, 32, and 109-121 are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 6, 2004